	Application No.	Applicant(s)	
Examiner-Initiated Interview Summary	09/439,534	MOLLER ET AL.	
	Examiner	Art Unit	
	Ashwin · Mehta	1638	
All Participants:	Status of Application: Allowed		
(1) <u>Ashwin Mehta</u> .	(3)		
(2) <u>Jeffrey Ihnen</u> .	(4)		
Date of Interview: 27 August 2003	Time:		
Type of Interview: ☐ Telephonic ☐ Video Conference ☐ Personal (Copy given to: ☐ Applicant ☐ Applicant Exhibit Shown or Demonstrated: ☐ Yes ☐ No If Yes, provide a brief description:	nt's representative)		
Part I.			
Rejection(s) discussed: None		·	
Claims discussed: 39, 46, 59	·		
Prior art documents discussed: None			
Part II.	•		
SUBSTANCE OF INTERVIEW DESCRIBING THE GENER Examiner's amendments to the claims were proposed and approve		S DISCUSSED:	
Part III.			
 It is not necessary for applicant to provide a separate redirectly resulted in the allowance of the application. The of the interview in the Notice of Allowability. It is not necessary for applicant to provide a separate redid not result in resolution of all issues. A brief summary 	examiner will provide a writte ecord of the substance of the	en summary of the substance interview, since the interview	
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(Examiner/SPE Signature) (Applicant/	Applicant's Representative Si	gnature – if appropriate)	

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Claim Rejections

- 1. The rejection of claims 39-46, 59, 60, and 72 under 35 U.S.C. 112, 1st paragraph, is withdrawn in light of the claim amendments or cancellations.
- 2. The rejections of claims 36-45, 59, 60, and 72 under 35 U.S.C. 103(a) are withdrawn, in light of the claim amendments or cancellations.

Examiner's Amendment

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jeffrey Ihnen on 27 August 2003.

The application has been amended as follows:

In the claims,

39. (Currently Amended) A plant transformation vector comprising a gene of interest, [at least one] a gene encoding a transcription factor, an inducible gene encoding a recombinase under the control of a <u>vertebrate</u> hormone inducible promoter system, and [at least one] <u>a</u> pair of recombination sites, wherein said recombination sites flank a marker gene.

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46. (Currently Amended) The vector of claim 39 [having at least two pairs of recombination sites, wherein a first pair of recombination sites flanks a marker gene] wherein said marker gene is under the control of a high affinity vertebrate hormone inducible promoter, and [a second pair of recombination sites flanks a recombinase gene] said inducible gene is under the control of a low affinity vertebrate hormone inducible promoter, wherein said high affinity vertebrate hormone inducible promoter is induced by a vertebrate hormone at a low concentration and said low affinity vertebrate hormone inducible promoter is induced by said vertebrate hormone at a high concentration.

- 59. In lines 2 and 3 of part c), the term, --vertebrate-- was inserted before "hormone".
- 4. The following is an examiner's statement of reasons for allowance: Applicants have developed a method for excising a marker gene from the genome of a germline cell of a transgenic plant. The method involves the use of a vector that comprises a gene of interest, a gene encoding a transcription factor, a gene encoding a recombinase comprising a promoter that is inducible by a vertebrate hormone, a marker gene, and a pair of recombination sites. The recombination sites, which are recognized by the recombinase, flank the portion of the vector that comprises the marker gene. The induction system exemplified in the specification is the GVG inducible system. The GVG transcription factor consists of the hormone-binding domain of the rat glucocorticoid receptor, the yeast Gal4 DNA-binding domain, and the transcriptional activator from the herpes viral protein, V16. The recombinase gene is operably linked to a promoter that comprises a Gal4 upstream activating sequence. The vector is introduced into

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plant cells and transgenic plants are regenerated. Following selection of transgenic plants expressing the marker gene, the chemical inducer dexamethasone is applied. Dexamethasone causes a conformational change to GVG, which can then recognize and induce promoters comprising the Gal4 upstream activating sequence, in this case the promoter of the recombinase gene. The expressed recombinase excises the nucleotide sequences that are flanked by the recombination sites. The dexamethasone is added at a time such that the excision occurs in germline cells, so that the marker gene is not passed on to the next generation. The prior art (Sugita et al., U.S. Patent No. 6,326,192) teaches a plant transformation vector that comprises a gene of interest, a morphological abnormality induction gene, and sequences that are flanked by substrates sites that are recognized by a site-specific recombinase. The morphological abnormality induction gene and the gene encoding the recombinase are located within the region flanked by the recombinase substrate sites. The morphological abnormality induction gene causes an abnormality in the transgenic plant. The prior art vector does not contain any other type of marker gene, and also does not comprise a gene encoding a transcription factor. Applicants also have provided their own post-filing publication (Zuo et al., Nature Biotech., 2001, Vol. 19, pages 175-161), which demonstrates the use of the instantly claimed vector and method with the use of a hormone promoter induction system based on the estrogen receptorbased fusion transactivator, XVE.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

August 27, 2003

Áshwin D. Mehta, Ph.D.

Primary Examiner

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